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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,051	04/26/2001	Martin T. Gerber	P-8436.03CIP1	8909

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/843,051	GERBER ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 8-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, and 11-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Speicher et al (4603705). Speicher is capable of meeting the functional use recitations presented in the claims since he use an implantable, flexible coil electrode, the electrode and lead are of a similar size and shape as the applicants invention, and since it meets the claimed limitations. In addition, Speicher meets the claimed limitation of "about 2 mm" since his coil diameter is "about 3 mm" (col 5). Also, Speicher shows the electrode connectors (20, 22, 50, or 52) connected to one another in connection zones or adhered to (dictionary definition of adhered of "to give support" or "to hold fast or stick by") since the coil electrode and connector are maintained in connection with each

other to provide the implantable lead. Finally, Speicher shows the claimed "at least one ring electrode" as the other coiled electrode or conductive electrode connectors 22, 20, 52, or 50 with the ring electrode and coiled electrode being capable of meeting the functional use recitation of providing electrical stimulation to the at least one sacral nerve since the electrode connectors (the claimed "ring electrode") are immediate adjacent to the coil electrode, since the claims say "at least one sacral nerve" which can mean one, two, three, or more, and since the claim does not say the nerve is stimulated "at the same time" or with the same pulse, etc. Nothing prevents the lead to stimulate with one electrode at one time and another electrode at another time to the same or different nerves.

In the alternative, Speicher discloses the claimed invention except for the coil diameter being from about 0.5 mm to about 2.0 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead with coil electrode as taught by Speicher, with a coiled electrode having a diameter of about 0.5 mm to about 2.0 mm since it was known in the art that implantable leads with coil electrodes use a coil electrode of about 0.5 mm to about 2.0 mm to provide an implantable lead having a coil electrode that is small and unobtrusive. In addition, one skilled in the art would have expected both the applicants claimed invention and Speicher's invention to have the same properties even though the ranges do not overlap since both are used for providing an implantable lead with flexible coiled electrodes. (According to MPEP 2144.05, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties).

Claims 3 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speicher et al.

Speicher discloses the claimed invention except for the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead with coil electrode as taught by Speicher, with the electrode and connector being butt-welded together since it was known in the art that implantable leads use a butt-weld to connect electrodes and connectors to provide a secure and easily produced connection to connect the two elements together.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the implantable lead as taught by Speicher with the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters, because Applicant has not disclosed that the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrode connector and coil electrode being connected together and the inner diameters not being substantially the same as taught by Speicher, because Speicher provides a coil electrode and connector that is flexible and implantable.

Therefore, it would have been an obvious matter of design choice to modify Speicher to obtain the invention as specified in the claim(s).

Claims 1, 2, 4, 8, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schear (6251107). Schaer provides a flexible coil electrode that can be intravascularly positioned and is of a similar size and shape of the applicant's invention and therefore is capable of meeting the functional use recitations presented in the claims. Also, any of the other coil electrodes can be considered to be the claimed "ring electrode" located proximal or distal to a coil electrode with the ring electrode and coiled electrode being capable of meeting the functional use recitation of providing electrical stimulation to the at least one sacral nerve since the other electrodes (the claimed "ring electrodes) are adjacent to the coil electrode, since the claims say "at least one sacral nerve" which can mean one, two, three, or more, and since the claim does not say stimulating the nerve "at the same time" or with the same pulse, etc. Nothing prevents the lead to stimulate with one electrode at one time and another electrode at another time to the same or different nerves.

But Schaer does not disclose an electrode connector connected/adhered in an annular connection zone to the electrode and mechanically and electrically connected to the conductor with the connector and electrode axially aligned and having substantially common outer and inner diameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead with flexible coil electrodes as taught by Schaer, with an electrode connector connected/adhered in an annular connection zone to the electrode and mechanically and electrically connected to the conductor with the connector and electrode axially aligned and having substantially common outer and inner diameters since it was known in the art that leads using flexible coil electrodes use an electrode connector connected/adhered in an annular connection zone to the electrode and mechanically and electrically connected to the

conductor with the connector and electrode axially aligned and having substantially common outer and inner diameters to provide a more secure connection of the conductor to the electrode that lessens /separation breakage of the conductor from the electrode, and allows the electrode to be securely attached to the electrode connector over the diameter of the electrode.

Response to Arguments

Applicant's arguments filed 6/15/05 have been fully considered but they are not persuasive.

The argument that Speicher or Schaer do not meet the functional use recitations in the claims is not persuasive since Speicher or Schaer both provide flexible implantable coil electrodes and ring electrodes that can/will stimulate "at least one" nerve. It is noted that "at least one" can mean one or more sacral nerves. In addition, Speicher and Schaer may stimulate multiple nerves since the lead can be moved from nerve to nerve to stimulate more than one nerve (as is common practice when testing for the correct nerve to stimulate). It is noted that the claims do not state "stimulating nerves with different electrodes" or "at the same time". Therefore, Speicher and Schaer are capable of meeting the functional use recitations presented in the claims. It is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136

USPQ 458, 459 (CCPA 1963). Also, the examiner has referenced Gotthardt as one teaching of many showing that a coil electrode is also considered to be a ring electrode.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762
12/26/5

GRE
December 26, 2005